

U. S. DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

**UNSOLICITED PROPOSALS
FOR MEDICARE
DEMONSTRATIONS:
A HOW TO KIT**

**OFFICE OF RESEARCH, DEVELOPMENT, AND
INFORMATION**



INTRODUCTION

This “how to” kit provides guidance for organizations that wish to submit an ***unsolicited proposal*** for a Medicare demonstration sponsored by the Centers for Medicare & Medicaid Services (CMS). Organizations that wish to submit proposals in response to a published solicitation for a Medicare demonstration should not use these instructions; rather, they should follow the instructions in the published solicitation.

What is a Medicare Demonstration?

CMS conducts Medicare demonstrations to test innovations that have the potential to improve the economy and efficiency of the Medicare program. Such improvements may include alternative approaches to health care payment and/or the delivery of health care services. CMS undertakes *demonstrations that are designed to test an improvement* that can be evaluated and, if successful, potentially incorporated into the Medicare program.

CMS has the authority under Section 402 of Pub. L. 92-603 to waive *only* payment and benefit provisions of the Medicare program to conduct demonstrations that increase the “efficiency and economy of health services...through the creation of additional incentives...without adversely affecting the quality of such services.” CMS does not have the authority to waive other provisions of the Medicare program such as conditions of participation for providers or beneficiary eligibility.

Given CMS’ limited resources to conduct demonstrations, unsolicited proposals are considered ***only*** if they have significant potential to improve the Medicare program.

Availability of CMS funds and budget neutrality

The President’s Office of Management and Budget routinely evaluates Medicare demonstrations for budget neutrality. Budget neutrality means that the expected costs under the demonstration cannot be more than the expected cost were the demonstration not to occur. Consequently, any additional costs to Medicare (for new services or payment approaches) must be offset by savings elsewhere in the program. CMS only pays for the provision of health care services to Medicare beneficiaries. Other costs, such as administrative overhead and start-up costs, should be factored into costs for services provided under the demonstration and should be included in the calculation of budget neutrality.

THE REVIEW PROCESS

Step One: Concept Paper Outline

To facilitate the review process, organizations should first submit a 3-5 page concept paper summarizing the proposed project and asking for CMS comments. The concept paper should:

1. Identify *contact persons* for the project

2. Explain the *purpose of the project*—its goals and objectives and/or research hypotheses.
3. Explain the *project's policy importance*—why the information gained from the project would be important to CMS; and how CMS support of this project is consistent with the Agency's goals.
4. Describe the *project research design, methodology or approach*—how will the project be designed and what methods will be used to gather data, accomplish the project's objectives, and measure the results of the demonstration.
5. Include a brief *work plan* that summarizes the major tasks/activities and a general timeline.
6. Summarize *resources* requested from CMS and how they would be used to carry out the project.
7. Provide an explanation of how the proposed payment methodology (including risk-taking) will be *budget neutral to Medicare*. Provide evidence, based on prior research, that the projected savings, quality improvement, and/or access improvement are likely to occur.

Step Two: CMS review of concept paper

ORDI will review the concept paper and provide comments to the applicant organization. The applicant should

provide a revised concept paper incorporating changes suggested by ORDI. ORDI will then provide a feasibility assessment of the project. Where ORDI assesses a proposal as feasible to proceed, the applicant may submit a demonstration application to ORDI.

Step Three: Demonstration application process

Once a decision has been made that a demonstration application is to be submitted, please follow instructions in the addendum below. Applications will be evaluated by an expert technical advisory panel. The panel will make recommendations to ORDI regarding the technical merits of the proposal. ORDI provides advice to the Administrator who decides whether or not to proceed with applications found technically acceptable.

Step Four: OMB approval

After a project has been approved by the Administrator, a waiver package is prepared for review and approval by the President's Office of Management and Budget (OMB). Demonstrations may not begin (i.e., federal funds are not available) until approval has been provided by OMB.

FOR FURTHER INFORMATION

Please contact the Office of Research,
Development, and Information at 410-
786-6507.

Send materials to:
Office of Research, Development, and
Information.
Centers for Medicare & Medicaid
Services.
C3-20-11, 7500 Security Blvd.,
Baltimore MD 21244-1850.

ADDENDUM: DEMONSTRATION APPLICATION MATERIALS

Demonstration applications *must* include the following information.

Cover Letter Please be sure to identify the demonstration, indicate the target population and geographic location of the demonstration (for example, urban or rural), the CMS provider numbers assigned to the applicant, contact person, and contact information.

Medicare Waiver Demonstration Applicant Data Sheet Complete, sign, date, and return the Medicare Waiver Demonstration Applicant Data Sheet.

Executive Summary Provide a 4 page summary of the key elements of the proposal.

Problem Statement Describe Medicare's current coverage and payment policy, and describe how or why changes to current policy would lead to reductions in Medicare expenditures or improvements in Medicare beneficiaries' access to and/or quality of care. Provide local examples. Describe the policy rationale for the proposal, who will benefit and why, and any previous experience with the proposed intervention.

Demonstration Design Describe the intervention including the scope of services covered and/or benefit design, beneficiary liability, and payment methodology including financial incentives and/or risk sharing arrangements. Indicate how eligible beneficiaries will be identified, targeted,

and enrolled in the demonstration (if applicable).

If applicable, describe the study design. Identify the intervention and comparison groups, and how Medicare beneficiaries will be assigned to each group. If a randomized study design is proposed, describe the process and provide a copy of the informed consent to be used.

Organizational Structure & Capabilities Describe your governance structure and management and clinical teams, and their success before implementing the proposed intervention. Provide an organizational chart that describes the functional and reporting lines of major departments and/or entities.

Demonstrate that infrastructure exists to implement and carry out the demonstration project. Provide copies of reports from clinical, financial, and management information systems and describe how they are used.

Provide copies of applicable Federal and State licenses. Indicate if the applicant is a Medicare provider in good standing. Describe any other applicable accreditation, credentialing, and/or certification processes and results.

Provide documentation of your organization's financial viability that will enable it to participate actively and successfully in the demonstration. For example, a formal audit opinion from the past 3 years or the balance sheet from the past 3 years with a summary description. If there are any financial concerns, explain how your organization has addressed or will address these problems.

Performance Results Describe your systems and processes for monitoring clinical, financial, and operational performance. Identify key metrics collected and describe how you use this information to continuously improve the proposed intervention, correct deficiencies, satisfy beneficiaries, providers, and/or payers.

Supplemental Materials Include copies of supporting materials requested or referenced throughout the application.

Payment Methodology & Budget Neutrality Indicate the proposed payment amount and method. Proposed payments may be based on fee-for-service or Medicare+Choice rates, methodologies, or some combination, and may involve risk sharing.

Describe in detail any risk sharing arrangements. Provide a revenue and expense statement by year for the life of the demonstration.

Demonstrate that the proposed intervention is budget neutral. Provide expected, best, and worse case scenarios. Include all supporting cost effectiveness, evidence, and assumptions used for the calculations.

Demonstration Implementation Plan Describe your implementation strategy, including tasks, resources, and timeline to implement the demonstration. Identify internal system and process modifications required to implement the demonstration. Describe your recruitment strategy and contingency plans for achieving beneficiary thresholds. Identify the individuals and staff responsible for implementing the demonstration and attach biographies.

